REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS & AMENDMENTS

As correctly stated in the Office Action Summary, claims 1-9 were pending in this application when last examined. Claims 2, 3, 5, 6, 8, and 9 have been examined on the merits, and stand rejected. Claims 1, 4, and 7 are withdrawn from consideration as being drawn to non-elected subject matter.

Table 1 of the Specification at page 11, lines 1-2 has been amended to provide the appropriate SEQ ID NOs as requested by the Examiner. The Specification has also been amended to replace the Sequence Listing of record with the attached substitute Sequence Listing which includes the sequence for the new SEQ ID Nos. Support for these amendments can be found in the originally filed Specification at the same locations and in the newly revised Sequence Listing.

Therefore, no new matter has been added by this amendment.

II. OBJECTION TO THE SPECIFICATION

The Specification has been objected to for failing to provide SEQ ID NOs for the amino acid sequences disclosed in Table 1 on page 11, lines 1-2. See Office Action, pages 2-3. Applicants respectfully traverse this objection in view of the foregoing amendments and the following remarks.

Enclosed is a new Sequence Listing that includes the previously omitted amino acid sequences as noted by the Examiner. The Specification has also been amended to include the appropriate SEQ ID NOs. In view of the foregoing amendments, the present objection is untenable and should be withdrawn.

III. REJECTION UNDER 35 U.S.C. §§ 101, 112, FIRST PARAGRAPH, LACK OF UTILITY

Claims 2, 3, 5, 6, 8, and 9 stand rejected under 35 U.S.C. § 101, as purportedly lacking utility. Consequently, claims 2, 3, 5, 6, 8, and 9 also stand rejected under 35 U.S.C. § 112, first paragraph, because the Specification allegedly lacks an enabling disclosure for how to use the claimed invention. See Office Action, pages 3-5. Applicants respectfully traverse this rejection for the following reasons.

The Specification discloses both a credible "asserted utility" credible and a credible "well-established utility" for the claimed polynucleotide sequence of SEQ ID NO:2 and the human nuclear protein of SEQ ID NO:1.

To satisfy the utility requirement under 35 U.S.C. § 101, the claims and the Specification must disclose either a credible "asserted utility" or a credible "well-established utility" for the claimed invention. M.P.E.P. § 2107.02.

A "specific asserted utility" is an explicit statement of "why the applicant believes that the invention is useful." M.P.E.P. § 2107.02. Such statements will usually explain the purpose of how the invention may be used. Ibid. A "substantial utility" defines a real world use. Ibid. Along these lines, ***only one*** credible assertion of specific and substantial utility for the claimed invention is necessary to satisfy the utility requirement. M.P.E.P. § 2107. Moreover, the ***threshold of utility is not high***. See Brenner v. Manson, 383 U.S. 519, 534 (1966). Thus, if the asserted specific and substantial utility is considered credible by one skilled in the art, a rejection based on lack of utility is inappropriate. M.P.E.P. § 2107.

Applicants submit that the Specification provides numerous specific and substantial credible asserted utilities regarding the claimed nucleotide sequence and the human nuclear protein it encodes. For instance, the Specification sets forth such uses as:

1. the use of the polynucleotide of SEQ ID NO:2 as a probe for the diagnosis of various diseases, such as cancer (Specification, page 1, lines 13-14);

2. the use of the polynucleotide of SEQ ID NO:2 as a source for gene therapy (Specification, page 1, lines 13-14);

3. the use of the polynucleotide of SEQ ID NO:2 in expression vectors to produce the human nuclear protein of SEQ ID NO:1 (Specification, page 1, lines 13-14);

4. the use of the human nuclear protein of SEQ ID NO:1 for the diagnosis and therapy of various diseases, including cancer (Specification, page 1, lines 11-12); and

5. the use of the human nuclear protein of SEQ ID NO:1 for the generation of antibodies with diagnostics and research application (Specification, page 1, 11-12).

Applicants submit that any one of the above asserted utilities for the claimed invention would have been recognized as credible by those skilled in the art at the time of the claimed invention for at least the reasons set forth below.

The Specification teaches that the claimed polynucleotide encodes a novel human nuclear protein consisting of 704 amino acids, which contains a WW domain, and which exists in cellular nuclei. The Specification further teaches that human nuclear proteins have well established functions, such as transcription factors, splicing factors, intranuclear receptors, cell cycle regulators, tumor suppressors, etc. Specification, page 1, lines 24-30. The Specification also teaches that the protein of the instant invention shares high homology with known human nuclear proteins. The Specification also establishes that the human nuclear protein encoded by the claimed polynucleotide contains a WW domain, and that it is well established that WW domains are contained in the cytoskeleton system in proteins participating in the signal transduction system, as well as in ubiquitin-protein ligase in the protein degradation system and in a transcription activator. Specification, page 2, lines 5-20, page 10, lines 20-23. Attached are the results of a keyword search for the term PubMed database "WW domain-containing protein" further supporting the well established uses of WW domain-containing proteins. The Applicants also found that the protein encoded by the claimed polynucleotide binds the c-terminal domain of RNA polymerase and is expressed in any tissue. Based on such findings, those skilled in the art clearly would recognize the functions/uses of a polynucleotide encoding a WW domain-containing protein.

It is well established that asserted utilities are ***presumed true***. M.P.E.P. § 2107.01 and *In re* Brana, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). To overcome the presumptive truth of the asserted specific utilities set forth in the specification, the Office must show by a ***preponderance***

of evidence that it is ***more likely than not*** that the asserted specific utility would be considered false by a person of ordinary skill. M.P.E.P. § 2107.01 and *In re* Corkill, 226 U.S.P.Q. 1005, 1008 (Fed. Cir. 1985).

Applicants submit that the Office has failed to overcome this presumption because no evidence or arguments have been presented to contradict the asserted utilities set forth in the Specification and above. In other words, the Office has not shown by a preponderance of evidence that it is more likely than not that the asserted specific utilities would be considered false by a person of ordinary skill in the art. Instead, the rejection relies upon the assertion that despite the high homology to known human nuclear protein, Applicant "never establishes the activity of the protein encoded by SEQ ID NO:2." See Office Action, page 4.

In the absence of any scientific evidence or apparent reasons why the claimed compounds do not possess the disclosed specific utilities, the allegation of utility in the Specification must be accepted as correct. *In re* Kamal, 158 U.S.P.Q. 320, 323 (C.C.P.A. 1968). Certainly, the Office has not provided evidence that ***all*** the asserted specific utilities and well established utilities would be reasonably doubted, are inherently unbelievable or involve implausible scientific principles.

In addition to the credible asserted utility described above, Applicants submit that the Specification provides numerous "credible well established utilities." A "well established utility" is a specific, substantial, and credible utility that must be immediately apparent to one skilled in the art based on the characteristics of the invention (e.g., properties or applications of a product or process). M.P.E.P. § 2107; *Guidelines for Examination of Applications for Compliance With the Utility Requirement*, 66 Fed. Reg. 1097, 1098 (Jan. 5, 2001). In other words, it must be well known, immediately apparent and implied by the specification based on the disclosure of the properties of the claimed invention, either alone or taken with knowledge of one skilled in the art.

In the instant case, the Specification satisfies the requirements for a "well established utility." As discussed above, the Specification discloses that the encoded protein is a human nuclear protein containing a WW domain and that it is well established that such proteins are participate in a variety of cellular functions, including signal transduction. One of skill in the art would immediately recognize that the claimed polynucleotide sequence and the human nuclear protein it encodes have "real world" value as markers to assess signal transduction in healthy

and/or diseased tissue. In this regard, the instant invention is useful in the development of laboratory markers, diagnostic agents and medicaments for diseases involving signal transduction.

Furthermore, the Specification also discloses antibodies prepared from the protein encoded by the claimed polynucleotide. Such antibodies would also be useful as tools to monitor signal transduction in healthy and/or diseased tissue.

It is well established that laboratory markers and diagnostic antibodies are well known and widely used in the biotechnology industry. Likewise, the use of proteins in assays to detect the presence or absence of disease is also well known. No evidence has been presented to discredit such utility. Along these lines, Applicants note that M.P.E.P. 2107.01 states that

> ...an assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventative measures or further monitoring.

Given that the use of the instant invention is analogous to the above example described in the M.P.E.P. as a credible utility, it is evident that at least one of the above-discussed utilities is credible. Thus, it would be inconsistent to maintain that the claimed invention lacks utility. Moreover, no evidence has been presented to contradict such a well established utility. Accordingly, one skilled in the art upon reading the disclosure would immediately recognize this well established utility as credible.

Therefore, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 101. Applicants further submit that in view of the above, the rejection under 35 U.S.C. § 112, first paragraph should also be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the present application is in condition for allowance and notice to that effect is hereby requested.

If it is determined that the application is not in condition for allowance, the Examiner is invited to telephone the undersigned attorney at the number below to expedite prosecution of the present application.

Respectfully submitted,

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ATTACHMENT TO AMENDMENT AND REPLY:

1. Sequence Listing

2. Keyword search for term "WW domain" in the PubMed database